

***Remarks***

Reconsideration of this Application is respectfully requested. Applicants respectfully request that the above amendment be entered after final because it is filed concurrently with a Request for Continued Examination under 37 C.F.R. § 1.114 and it places the claims in better form for allowance. *See* 37 C.F.R. § 1.116(a).

Upon entry of the foregoing amendment, claims 36-37 and 39-42 are pending in the application, with claims 36 and 42 being the independent claims. Claim 36 is sought to be amended to clarify the scope of the claim. New claims 39-41, which depend from claim 36, and independent claim 42 are sought to be added. Support for new claims 39-40 may be found, *inter alia*, at page 8, lines 27-28; page 15, lines 26-31; and lines 24-26, page 32 of the specification and the claims as originally filed. Support for new claim 41 may be found, *inter alia*, at lines 8-9, page 32 of the specification and Figure 5A. New claim 42 is an independent claim incorporating the subject matter of claims 36, 40 and 41. As such, these changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Information Disclosure Statement***

Applicants thank the Examiner for initialing references AR52 and AR67 on Form PTO-1449 and for indicating in the official file wrapper that these documents have been considered.

***Rejections Under 35 U.S.C. § 112, First Paragraph - Enablement***

The Examiner has maintained the rejection of claims 36-37 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. *See* Office Action at page 2. Specifically, the Examiner indicates that "...there is no evidence that inhibition of cross-linking mediated by redox-reactive metals would have a positive impact on the course of AD" and that "[t]he sole working examples in the specification, as originally filed, pertain to the copper induced aggregation of A $\beta$  peptide in vitro, which is abolished by mannitol." Office Action at pages 3 and 4.

Applicants respectfully disagree for at least the reasons provided in the Amendment and Reply Under 37 C.F.R. § 1.111 filed on March 22, 2007. However, solely to advance prosecution, and not in acquiescence to the Examiner's rejection, Applicants have amended claim 36 to clarify that the claim is directed to a method for the identification of an agent that inhibits redox-reactive metal-mediated crosslinking of A $\beta$ . Thus, Applicants submit that the present amendment renders the Examiner's rejection moot.

Applicants traverse the rejection as it may apply to the claims as amended. The test for enablement is whether the disclosure when filed contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). The specification provides clear and unambiguous guidance regarding the methods of the claims as amended. For example, methods for identification of an agent capable of inhibiting redox-reactive metal-mediated crosslinking of A $\beta$  are explicitly disclosed at line 16, page 11 to line 5,

page 12 of the specification. Related methods for the identification of an agent are also provided at lines 1-18, page 6; lines 5-22, page 7; and lines 9-26, page 8 of the specification.

Specific examples of the claimed methods are also described. In particular, Example 1 describes the specific method of preventing Cu(II)-induced A $\beta$  aggregation with mannitol. Example 3 describes a related screening method to identify an agent that does not inhibit the ability of A $\beta$  to scavenge superoxide, as measured by superoxide dismutase (SOD)-like activity. This example provides further guidance for the claimed methods because one of skill in the art would know that A $\beta$  peptides exhibit Cu- and Fe-dependent activity similar to that of SOD. *See* line 27, page 22 to line 3, page 23 of the specification.

Applicants further note that while the existence of a working example is a factor to be considered, compliance "with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." M.P.E.P. § 2164.02. It is clear that an Applicant need not have actually reduced the invention to practice prior to filing. *See In Gould v. Quigg*, 822 F.2d 1074, 1078 (Fed. Cir. 1987); *In re Borkowski*, 422 F.2d 904, 908 (CCPA 1970); M.P.E.P. § 2164.02.

Experimentation does preclude patentability; only when that experimentation is considered undue can a rejection be properly maintained. Applicants submit that given the guidance provided in the specification, along with the knowledge and high degree of skill available in the art, the skilled artisan could make and use the claimed invention without undue experimentation. *See United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the

art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987)("[a] patent need not teach, and preferably omits, what is well known in the art."). Therefore, Applicants assert that the scope of enablement is commensurate with the scope of the claims.

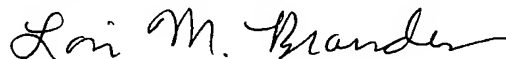
### ***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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